

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

_____)
IN RE: NEW ENGLAND) MDL No. 2419
COMPOUNDING PHARMACY, INC.)
PRODUCTS LIABILITY) Master Dkt.: 1:13-md-02419-FDS
LITIGATION)
_____) U.S. District Judge F. Dennis Saylor, IV
THIS DOCUMENT RELATES TO:)
)
All Actions)
_____)

**OBJECTIONS OF NON-PARTY, ALLEGHENY PAIN MANAGEMENT, P.C.,
TO PLAINTIFFS' STEERING COMMITTEE SUBPOENA**

NOW COMES Allegheny Pain Management, P.C. ("Allegheny"), having previously filed its Notice of Limited Appearance, and files its Objections to Subpoena, as follows:

I. PROCEDURAL HISTORY AND BRIEF OVERVIEW

Allegheny is a medical practice located in Altoona, Pennsylvania. Allegheny has received a subpoena from the law firm Hagens Berman, on behalf of the Plaintiffs' Steering Committee ("PSC") in conjunction with the above-captioned multi-district litigation. The subpoena was sent under cover letter dated June 21, 2013. The cover letter lists an address for Allegheny but gives no indication as to manner of transmittal. To the best knowledge,

information and belief of Allegheny, the cover letter and subpoena was received on or about June 26, 2013 and was delivered via regular U.S. Mail or overnight mail. It was not personally served. A true and correct copy of the cover letter and subpoena is attached hereto as Exhibit "A".

Not only is Allegheny a non-party to this action, but patients of Allegheny have not demonstrated any adverse reaction to any products from the New England Compounding Pharmacy.

II. SUBSTANCE OF SUBPOENA

The subpoena issued upon Allegheny includes 21 separate, full-paragraph requests, which are set forth at Exhibit "B" to subpoena, and are summarized / excerpted below:

- (1) "Any and all documents...**related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA")**...from NECP, for the time period October 6, 2010 – October 6, 2012.
- (2) "Any and all documents...related in any way whatsoever to, the procurement of MPA, **or its generic or name-brand equivalent** from any producer...." since October 6, 2007.
- (3) "Any and all documents...related in anyway whatsoever to the procurement of **cardioplegic solution** from NECP....", for the time period October 6, 2010 – October 6, 2012.
- (4) "Any and all documents...related in any way whatsoever to the procurement of **ophthalmic solution** from NECP....", for the time period October 6, 2010 – October 6, 2012.
- (5) "Any and all documents...related in any way whatsoever to the procurement of preservative-free **saline solution** from NECP....", for the time period October 6, 2010 – October 6, 2012.
- (6) "Any and all documents...reflecting...the identification of **each and every patient** that was administrated an NECP product..." for the time period October 6, 2010 – October 6, 2012
- (7) "Any and all documents...reflecting or containing **communications** (written or otherwise) **between Allegheny Pain Management, P.C....and NECP...**" for the time period October 6, 2010 – October 6, 2012.
- (8) "Any and all documents...containing information obtained...regarding NECP, including without limitation of the foregoing, **NECP's qualifications, certifications or accreditations**, or lack thereof, regulatory

- compliance...suitability for conducting its business, legal actions and/or warnings (etc).”
- (9) “Any and all documents...containing information obtained by...the Healthcare Provider...concerning the **fitness of any products** purchased or obtained by NECP...” for the time period October 6, 2010 – October 6, 2012.
 - (10) “Any and all documents...containing information obtained by...the Healthcare Provider...**from the (CDC), (FDA) and/or other Federal, state or local regulatory agency**, concerning the fitness of any products manufactured compounded or **produced by NECP.**”
 - (11) “Any and all documents...containing information obtained by...the Healthcare Provider...from any federal or state agency...in connection with the procurement of products **from any compounding pharmacy.**”
 - (12) “Any and all documents...containing **marketing information** from NECP....”
 - (13) “Any and all documents...containing **agreements, contracts and/or warranties** between the Healthcare Provider and NECP....”
 - (14) “Any and all documents...containing **recall notices** received by the Healthcare Provider pertaining to products produced by NECP....”
 - (15) “Any and all documents...reflecting **communications** made or issued by the Healthcare Provider...**in response to any recall notice** regarding NECP....”
 - (16) “Any and all documents regarding any **investigation** or inquiry the Healthcare Provider performed **related to attempts by NECP to comply** with the United States Pharmacopeia – National Formulary, Chapter 797....”;
 - (17) “Any and all **policies of** insurance...for the policy periods including calendar years 2011, 2012, and 2013.”
 - (18) “**Articles of Incorporation and/or By-Laws** applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.
 - (19) “Any and all documents...containing the **names and addresses and positions** (President, Vice-President, Director, etc.) **within the Healthcare Provider**...during the calendar years 2011, 2012, and 2013.”
 - (20) “Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.”
 - (21) “Any and all **organizational charts** maintained by the Healthcare Provider....”

(emphasis added)

III. ARGUMENT

- A. **The Subpoena should be quashed, entirely or in part, for failing to comply with this Court’s Order of June 21, 2013, “GRANTING PLAINTIFFS LEAVE TO SERVE SUBPOENAS AND QUALIFIED PROTECTIVE ORDER REGARDING PROTECTION OF HEALTH INFORMATION.”**

On June 21, 2013, this Court entered an "Order Granting Plaintiff's Leave to Serve

Subpoenas and Qualified Protective Order Regarding Protection of Health Information".

This Court established a process and a defined scope of inquiry, as follows:

2. The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January 2011 - November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

(See June 21, 2013 Order, Dkt. No. 192, at 112.).

The Court's order may be broken down as follows. The PSC may seek the following information:

- (1) Names and addresses of patients who received NECC medications from January 2011 – November 2012;
- (2) Records identifying NECC as the supplier, including order forms, prescriptions, and billing records;
- (3) NECC product storage and patient distribution records; and
- (4) Any other information determined by PSC counsel to be "reasonably necessary to the prosecution and resolution of these actions."

Many of PSC's requests exceed the scope of permitted discovery. The Court permitted the discovery of patient names and NECC purchase records related to those patients for the period of January 2011 through November 2012, yet the subpoena documents going as far back as October 6, 2007 and patient names for the period of October 6, 2010 through October 6, 2012. As can be plainly seen in the summary of the subpoena set forth above, MSC seeks a wide array of information, far beyond the bounds of permitted discovery, including:

- Information concerning the purchase of MPA and other products from NECP;

- Information relating to NECP's qualifications or certifications;
- Information relating to the fitness of any products from NECP, or its generic equivalents;
- Information from the CED, FDA, or other agencies regarding NECP "or any compounding pharmacy";
- Marketing information, agreements, contracts, etc. regarding NECP;
- Recall notices and related items;
- Allegheny's insurance policies for a three year period;
- Allegheny's corporate documents, officers list, and organizational charts.

PSC's requests are clearly far beyond the bounds of limited discovery prescribed by this Court.

B. The Subpoena should be quashed, entirely or in part, on the basis that the requests for information are overly broad, and seeks information that is not relevant.

A review of the above-summary of the items requested by the subpoena readily reveals that PSC's requests are overly broad and compliance therewith by Allegheny would require a tremendous amount of time and resources. Furthermore, given that Allegheny is a non-party, PSC's subpoena seeks information that is neither relevant nor reasonably calculated to lead to the discovery or relevant evidence. Pa.R.C.P. 26(b)(1). In particular, requests regarding Allegheny's insurance policies and organization structure are clearly irrelevant in this multi-district litigation. The request for information regarding other compounding pharmacies is also outside the scope of reasonable relevance. PSC is obviously involved in a fishing expedition and is seeking to hook more clients.

C. The Subpoena should be quashed, entirely or in part, on the basis that Allegheny cannot comply without violating HIPAA.

Much of the information requested by PSC is Protected Health Information and Erlanger cannot provide the requested information or else it would be in violation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. § 164.501 *et seq.* HIPAA

requires a covered entity, such as Allegheny, to keep patients' Protected Health Information confidential and not disclose that information to a third-party except under specific circumstances. Furthermore, the QPO specifically states that "[t]he information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions ..." (Dkt. No. 192). Allegheny cannot be forced to violate federal law in order to comply with this subpoena; and further, PSC must follow this Court's directive.

D. The Subpoena should be quashed, entirely or in part, on the basis that same may be construed as seeking information protected from disclosure from the attorney-client privilege.

Given the breadth of PSC's requested, some of the information sought may be protected from disclosure from the attorney-client privilege, particularly number 15 and 16, which seek all communications on the subject of the recall.

E. The Subpoena should be quashed, entirely or in part, on the basis that the information may be obtained from other sources.

Many of the documents requested by PSC may easily be obtained from other, more appropriate sources, such as the FDA, CDC, and/or the Pennsylvania Department of Health. This factor may be considered by this Court in determining the merits of Allegheny's objections.

F. The Subpoena should be quashed, entirely, for improper service.

Fed. R. Civ P. 45(b)(1) requires service of the subpoena by personal service. In this case, to the best knowledge, information and belief of Allegheny, the subpoena was served either by overnight mail or U.S. mail. It was not hand-delivered. Thus, service was deficient.

G. The Subpoena should be quashed, for lack of jurisdiction.

It is respectfully submitted that Allegheny, a Pennsylvania corporation, is not subject to the jurisdiction of this Court, particularly given the failure of proper service.

H. The Subpoena should be quashed, entirely, for failure to provide the required witness fee.

PSC has failed to provide the witness fee, as required by Fed.R.Civ.P 45(b)(1). Service is therefore defective.

I. The Subpoena should be quashed, entirely, for failure to comply with the Order of this Court requiring that the Qualified Protective Order be appended to the subpoena.

At paragraph 15 of this Court's Order of June 21, 2013 (docket No. 192), it is stated: "A copy of this Order shall be appended to the subpoenas." MSC failed to do so.

J. The Subpoena should be quashed entirely for failure to provide a reasonable period of time in response.

Allegheny believes the subpoena was delivered on or about June 26, 2012. The response date, now-passed, was July 15. It is submitted that this is an inadequate time to respond to such a lengthy document request. Further, to the extent that the subpoena is not quashed in its entirety, it is requested that an appropriate response period be granted to Allegheny.

Respectfully submitted,

McQUAIDE BLASKO, INC.

Dated: July 19, 2013

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the Objections of Non-Party, Allegheny Pain Management, P.C., to Plaintiffs' Steering Committee Subpoena in the above-captioned matter was served via ECF this 19th day of July, 2013, to the attorneys/parties of record.

McQUAIDE BLASKO, INC.

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